

WHAT IS CLAIMED IS:

Sub A1

1. A vaccine formulation for oral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles sized such that at least 50% of the microparticles are less than 5 μm , the microparticles comprising at least one antigen entrapped or encapsulated by a biodegradable polymer.

a

method
2. The vaccine formulation of Claim 1, wherein the microparticles are sized such that at least 50% of the microparticles are less than 3 μm .

Sub A2

3. The vaccine formulation of Claim 1, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid or enantiomers thereof.

4. The vaccine formulation of Claim 1, wherein the microparticles are formed using a solvent evaporation method.

a

method
5. The vaccine formulation of Claim 1, wherein the antigen comprises a *B. pertussis* antigen.

a

method
6. The vaccine formulation of Claim 1, wherein the microparticles comprise at least 2 subpopulations of microparticles, each subpopulation comprising a different antigen entrapped or encapsulated by a biodegradable polymer.

Sub A3

7. A vaccine formulation for oral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of nanoparticles sized such that at least 50% of the nanoparticles are less than 600nm, the nanoparticles comprising at least one antigen entrapped or encapsulated by a biodegradable polymer.

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SUB
D1

method
8. The vaccine formulation of Claim 7, wherein the nanoparticles are sized such that at least 50% of the microparticles are less than 500nm.

Sub A. 4
9. The vaccine formulation of Claim 7, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid or enantiomers thereof.

10. The vaccine formulation of Claim 7, wherein the nanoparticles are formed using a coacervation method.

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11. ~~The vaccine formulation of Claim 7, wherein the antigen comprises a *B. pertussis* antigen.~~ ^{method}

a sub D
12. ~~The vaccine formulation of Claim 7, wherein the nanoparticles comprise at least 2 subpopulations of nanoparticles, each subpopulation comprising a different antigen entrapped or encapsulated by a biodegradable polymer.~~ ^{method}

Sub A. 5
13. A method of inducing a protective immune response against *B. pertussis*, comprising orally administering to a subject a pharmaceutically effective amount of microparticles sized such that at least 50% of the microparticles are less than 5 μm , the microparticles comprising at least one *B. pertussis* antigen entrapped or encapsulated by a biodegradable polymer.

14. The method of Claim 13, where the microparticles are sized such that at least 50% of the microparticles are less than 3 μm .

Sub A. 6
15. The method of Claim 13, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid and enantiomers thereof and wherein the microparticles are formed using a solvent evaporation method.

16. The method of Claim 13, wherein the at least one *B. pertussis* antigen is selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA), pertactin and fimbriae and combinations thereof.

17. A method of inducing a protective immune response against *B. pertussis*, comprising orally administering to a subject a pharmaceutically effective amount of nanoparticles sized such that at least 50% of the nanoparticles are less than

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